AUG 2 9 2001

Section 2 - Summary of Safety and Effectiveness

K003198

Manufacturer
ORATEC Interventions, Inc.
3700 Haven Court
Menlo Park, CA 94025

Contact Person
Linda Guthrie
Manager, Regulatory Affairs and Compliance

Device Name
Vulcan TAC Probes, Class II device (21 CFR 878.4400)

Generic/Common Name
Electrosurgical cutting and coagulation device and accessories

Device Description
The Vulcan TAC Probes are single-use, monopolar, electrothermal devices intended for coagulation and cutting of soft tissues. The TAC probes have an insulated shaft with a thermally conductive metal tip electrode. The proximal end of the shaft is attached to a handle made of an injection molded, medical grade plastic. There is also a T-type thermocouple inside the tip of the probe for monitoring temperature.

Technological Characteristics
ORATEC is requesting clearance to modify the device's existing general indications for use to more specific indications for use. There was no actual physical change to the device as a result of the proposed modified indications for use statement and, therefore, no changes to the technological characteristics.

Indications for Use
The Vulcan TAC Probes are disposable monopolar electrothermal probes and are intended to be used in combination with the Vulcan Generator for general surgical use, including orthopedic and arthroscopic applications for hemostasis of blood vessels, and in the controlled electro-coagulation of soft tissues in joints including but not limited to the knee, shoulder, wrist, hip, etc. The electro-coagulation of ligamentous tissue in the shoulder results in tissue contraction (shrinkage). Arthroscopic surgery could include a variety of procedures.

Predicate Device(s)
Indication for Use: Vulcan Electrosurgical Probes, K000691, cleared May 15, 2000

Substantial Equivalence Determination
The modified indications for use for the TAC Probes are substantially equivalent to the predicate device. This determination is based on the following:

1. the indications for use, as modified for the TAC Probes are equivalent to that of the predicate device and;
2. no new risks have been introduced as a results of the modification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2001

Ms. Linda Guthrie
Senior Regulatory Affairs Specialist
ORATEC Interventions, Inc.
3700 Haven Court
Menlo Park, California 94025

Re: K003198
Trade/Device Name: Vulcan® TAC™ Probe Family
Regulation Number: 888.1100, 878.4400
Regulatory Class: II
Product Code: HRX, GEI
Dated: May 31, 2001
Received: June 1, 2001

Dear Ms. Guthrie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K003198

Device Name: Vulcan® TAC™ Probe Family

Indications for Use: The Vulcan TAC Probes are disposable monopolar electrothermal probes and are intended to be used in combination with the Vulcan Generator for general surgical use, including orthopedic and arthroscopic applications for hemostasis of blood vessels, and in the controlled electro-coagulation of soft tissues in joints including but not limited to the knee, shoulder, wrist, hip, etc. The electro-coagulation of ligamentous tissue in the shoulder results in tissue contraction (shrinkage). Arthroscopic surgery could include a variety of procedures.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003198